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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,068	05/31/2001	Brian K. Courtney	MAC1001U	1810

20350 7590 06/29/2005

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EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5/10

Office Action Summary	Application No.		Applicant(s)	
	09/872,068		COURTNEY ET AL.	
	Examiner		Art Unit	
	Michael J. Hayes		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-13,15-17,67 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-13,15-17,67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/07/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the filter introduced through the treatment port and the outer shaft lumen as recited in claim 13 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Fig. 17 shows the filter through the inner shaft lumen, not the outer shaft lumen.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 9, 10, 13, 15, 67, and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Dubrul (US Patent No. 6,287,271). Dubrul discloses a catheter having an outer shaft, expandable occluder, efflux port in communication with outer shaft lumen, inner shaft, influx port in fluid communication with inner shaft lumen, treatment port for access to outer shaft lumen, means for varying fluid flow rates through the ports and within the patient's vessel, guidewire in the inner shaft lumen, a source of contrast fluid, and a filter positioned through the treatment port. See figs. 12-18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over CONSTANTZ et al. (US Patent No. 6,527,979). Constantz discloses a catheter having an

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outer shaft, expandable occluder, efflux port in communication with outer shaft lumen, inner shaft, influx port in fluid communication with inner shaft lumen, treatment port for access to outer shaft lumen, and a balloon catheter that is capable of delivering a stent or performing angioplasty. See figs. 3b, 4b. Constantz discloses different embodiments showing an inner shaft without a distal occlusion balloon having a longitudinally directed rinse hole (figs. 6-10) and an inner shaft having side infusion rinse holes. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the side rinse holes in the embodiment without the inner shaft distal occlusion balloon in order to direct the infused fluid sideways to the walls of the vessel to achieve greater infusion fluid coverage within the vessel.

Claims 2, 3, 6, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul as applied to claim 1 above, and further in view of DAVIS et al. (US Patent No. 6,068,608). Dubrul discloses the claimed invention except for inflation passage in wall or separate shaft, occluder of open-cell foam enclosed by sheath. Davis teaches the use of an inflation passage in wall and occluder of open-cell foam enclosed by sheath to isolate a volume within a patient to facilitate surgery and therapeutic treatment. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Davis in the catheter of Dubrul to occlude body passageways of varying diameters and to have the occluder expand using minimal catheter width. The separation of the inflation lumen from the wall would be obvious to one of ordinary skill in the art because it merely changes the wall from a unitary structure into plural structures.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over DUBRUL or CONSTANTZ and further in view of KOKISH et al. (US Patent No. 6,485,500).

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Dubrul or Constantz disclose the claimed invention except for a stent delivery or angioplasty catheter introduced through a treatment port. Kokish discloses a stent delivery or angioplasty catheter introduced through a treatment port to perform the desired procedure (figs. 5-10). The catheter balloon is capable of delivering a stent or performing angioplasty because of its ability to apply pressure to the vessel walls. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kokish in the inventions of Dubrul or Constantz in order to perform additional desired procedures through a single outer catheter.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over DUBRUL or CONSTANTZ and further in view of TUSUGITA (US Patent No. 6,168,579). Dubrul or Constantz disclose the claimed invention except for a filter introduced through a treatment port. Tusugita discloses a filter 20 that is introduced through a treatment port along with an inner shaft. See fig. 3B, col. 6, ll. 14-24. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Tusugita in the inventions of Dubrul or Constantz in order to entrap and remove embolic material from the vessel during endovascular procedures.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul as applied to claim 1 above, and further in view of DAVEY (US Patent No. 6,432,091). Dubrul discloses the claimed invention except for a distal end with flexible seal to form a seal around a guidewire. Davey teaches a distal end with flexible seal to form a seal around a guidewire (figs. 5, 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Davey in the invention of Dubrul in order to prevent fluid from leaking into the lumen while the guidewire was in place to position the catheter.

Response to Arguments

Applicant argues that Dubrul does not show an efflux port on an adaptor on a catheter system nor a treatment port for receiving an inner shaft. Applicant further argues that removal and exchange of the inner shaft is not achievable. The examiner disagrees. Applicant does not recite removal and exchange in the claims, but rather only that the treatment port removably receives the inner shaft. Additionally the examiner sees the prior art as disclosing an efflux port (port connected to element 110 in fig. 12), a treatment port (port through which inner shaft 10 extends in hub adapter shown in fig. 12), and an influx port described in col. 4, ll. 49-63 or col. 8, ll. 30-38. Dubrul discloses an inner shaft that delivers fluid within a patient's vessel distal of an occlusion balloon. The delivery of this fluid would require an influx port into the inner shaft and the placement of the inner shaft within the catheter system would require a treatment port.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

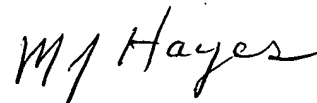
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
25 June 2005



MICHAEL J. HAYES
PRIMARY EXAMINER